Part 2 – Remarks

This Amendment and Response responds to the Office Action mailed March 30, 2009. A Request for Continued Examination (RCE) and the fee therefor accompanies this Amendment and Response. A Notice of Appeal, Petition for Two Months Extension of Time and a Pre-Appeal Brief Request for Review, along with the requisite fees, were filed on August 28, 2009. A Notice of Panel Decision from the Pre-Appeal Brief Review was mailed on October 27, 2009. The Notice of Panel Decision established a time for appeal of one month from the mailing of the Notice, thereby establishing November 27, 2009 as the appeal brief or response date. This Amendment and Response, accompanied by the RCE, was filed before November 27, 2009.

In the March 30 Office Action, claims 1, 5, 8 and 9 were rejected under 35 USC 103 as obvious from Rioux (US patent 6,494,855) in view of Ressemann (US patent 5,466,222); claims 10-12, 20-26, 30, 31, 33-37, 40, 44, 45 and 47 were rejected under 35 USC 103 as obvious from Rioux and Ressemann in view of Devonec (US patent 6,290,666); and claims 27 and 38 were rejected under 35 USC 103 as obvious from Rioux, Ressemann and Devonec in view of Ewers (US patent application 2001/0056273).

Reconsideration of these rejections is respectfully requested, in view of the amendments to the claims set forth above in Part 1 and the following comments.

Claims 1, 5, 8-11, 20-27, 31, 33-36, 38, 44, 45, 47 and 92-95 are pending.

Claim Amendments and New Claims

Claims 1 and 34 have been amended to provide an antecedent basis for the "use position" recited in some of their dependent claims. The use position now recited in claims 1 and 34 was originally described in the specification at page 6, lines 8-10.

Claims 10 and 34 have been amended to add the subject matter from canceled claims 30 and 37, respectively.

Claim 34 has been amended to recite that the insertion tool is formed as a flexible tubular structure. The original description of this subject matter appears at page 15, line 14. Claim 34 and its dependent claims have been amended to refer to the flexible tubular structure instead of the insertion tool.

Claims 10 and 34 have also been amended to recite that the inflation tube extends along the exterior of the insertion tool and the flexible tubular structure. This claim feature was previously recited in claims 10 and 34 in regard to the coiled section, is described in the specification at page 11, lines 5-14 and page 13, lines 16-19, and is shown in Figs. 1, 5-8 and 10.

The subject matter added to claim 21 was obtained from canceled claim 12.

The subject matter of new claims 92 to 95 is described in the original specification at page 15, line 27; page 15, line 31 and page 16, line 5.

It is submitted that no new matter has been added by these amendments.

Obviousness Rejections

The three rejections asserted in the March 30 Office Action are identical to the rejections asserted in the September 19, 2008 Office Action, except for the substitution of Ressemann for Anderson (US patent 4,813,935) in those rejections. The Examiner has acknowledged that the arguments in response to the September 19, 2008 rejections were "persuasive." See March 30 Office Action, paragraphs 13 and 23. The rejection has been continued because Ressemann was substituted for Anderson.

For the following reasons and others, it is respectfully asserted that Ressemann in combination with Rioux, Devoned and Ewers does not obviate the claims. The shortcomings of Rioux, Devonec and Ewers have been discussed in the January 21, 2009 response and those comments are hereby repeated and incorporated herein.

I. Ressemann is not applicable to the claimed subject matter. Guidance for its combination with Rioux, Devonec and Ewers is absent.

Ressemann deploys a catheter within vasculature (col. 2, lines 44-58, especially lines 51-54, wherein the catheter is inserted within restricted vessel). Ressemann does not suggest deploying the catheter within a urinary system.

This being the case, there is no evidence of guidance to the ordinarily skilled person for combining Ressemann with Rioux, Devonec or Ewers, singlularly or in combination, since the latter three references relate to devices for use in the urinary system.

II. Combining Ressemann with Rioux, Devonec or Ewers fails to meet the scope of the claims.

Ressemann does not use the coiled inflation tube to anchor the catheter, since sheath 32 prohibits the coiled tube 31 from contacting the vessel wall (col. 5, lines 5-18, especially lines 5-11, Fig. 5, sheath 32 between coiled tube 31 and vessel wall). Coiled tube 31 instead accommodates longitudinal length changes in the collapsible section 22.

Ressemann describes an angioplasty catheter inserted in a blood vessel. The catheter 10 has a longitudinally compressible section 22 used to shorten the catheter length so that it can be inserted over and removed from a guide wire 17 that is used to manipulate the catheter in the vessel. A coiled tube 31 in the compressible section 22 supplies fluid to a balloon 12. The balloon 12 is inflated in the vessel to expand and open the occlusion. A sheath 32 covers the coiled tube 31 (col. 5, lines 5-33). A rigid actuating member 16 extends through the collapsible section and is connected at an exterior manifold 13 to establish the length of the catheter (col. 4, lines 23-28; col. 5, lines 8-9, 22-29 and 46-52) and to anchor the catheter in place. In some embodiments, the actuating member is also the inflation conduit.

Ressemann's catheter is intended to slide into and out of the vessel without damaging it, so no aspect of the catheter, including the collapsible section 22, should create significant friction, resistance or anchoring force on the vessel. Furthermore, the sheath 32 prohibits the coiled tube 31 from contacting the vessel wall. Restraint of the catheter occurs outside of the vessel and outside of the patient by the connection of the actuating member to the external manifold. The purpose of the coiled tube 31 is to accommodate longitudinal length changes in the collapsible section 22, not anchoring.

The rejections rely only on Ressemann as the basis for anchoring the catheter with the inflation tube. "In the new grounds for rejection, Ressemann teaches an example of a coiled inflation tube used to anchor a catheter within a tubular vessel." March 30 Office Action, paragraph 27; also see page 3, line 16 to page 4, line 21; page 12, line 17 to page 12, line 7; and paragraphs 15, 16, 20, and 28. However as described above, Ressemann does not teach or suggest anchoring. Ressemann can not, therefore, teach or suggest the urinary canal anchoring limitations of lines 23-27 of claim 1 or lines 24-28 of claim 34.

Even if Ressemann was validly combined with Rioux, Devonec and Ewers, that combination would still not reach the scope of the pending claims.

III. The rejections are based on numerous mistaken and unsupported assumptions.

A. "It is the examiner's position that modifying Rioux in view of Ressemann places helical tube 31 of Ressemann adjacent to and proximal of the sphincter muscle." March 30 Office Action, page 4, lines 4-6. The Examiner's stated position implicitly acknowledges that there is no evidence which explains or guides where to place the helical coil 31 of Ressemann to function as a restraint for a urinary catheter. While Rioux does show a restraint 20 at the appropriate location downstream of the external urinary sphincter muscle, nothing in Rioux or Ressemann describes or suggests that Ressemann's non-restraining helical coil 31 should replace Rioux's tubular restraint 20. Ressemann's coil 31 could just as easily have been substituted for any number of other parts of Rioux. It is only the Applicant's disclosure that teaches the use of the coiled section of the inflation tube as the restraint.

B. The Examiner asserts that the "helical coil tube 31 (of Ressemann) (is) capable of maintaining axial shape and therefore restraining against distal movement." March 30 Office Action, page 4, lines 9-10. What evidence is the Examiner relying on to equate maintaining an axial shape with restraining against distal movement? Certainly not Ressemann, because Ressemann uses an actuating member restrained exterior of the patient at a manifold to hold the angioplasty catheter in place. Indeed, even the Applicant's disclosure does not equate maintaining an axial shape and restraining against axial movement. A coiled section of the inflation tube is disclosed and claimed as the restraint.

C. The alleged motivation for combining Rioux and Ressemann is that "both (references) anchor a catheter within a tubular physiologic vessel." March 30 Office Action, page 4, lines 10-12. Why change the separate, perfectly adequate, unrelated and vastly-different anchoring structure of Rioux for the non-restraining coil of Ressemann? The fact that both Rioux and Ressemann may extend in a tubular physiologic vessel is no motivation for specific change. Again, it is only the Applicant's disclosure that teaches using the coiled section of the inflation tube as the restraint.

D. A further alleged motivation to combine Rioux and Ressemann is to "consolidate the number of parts while both inflating a lumen and anchoring a catheter." March 30 Office Action, page 4, lines 20-21. This assertion begs the question of obviousness. The rejection assumes a motivation to consolidate parts, but no such consolidation is evidenced by Rioux or Ressemann. Rioux connects a separate restraint 20 to the main catheter body 10 by a separate tie 5 or 18, completely independently of the inflation tube 3. If anything, Rioux stands for parts proliferation, not consolidation, due to its separate restraint and separate connector. Ressemann retains the angioplasty catheter outside of the blood vessel and outside of the patient, to avoid injuring damaging the vessel. Consolidating Ressemann's exterior restraint to a restraint within the vessel is in conflict with his intended objective of avoiding damage to the vessel, except at the occlusion. It is only the Applicant's disclosure that teaches a consolidation of parts rationale. For the Examiner to invoke the Applicant's motivation as a basis for the rejection, absent evidence of similar independent motivation shown in the prior art, confirms the improper use of hindsight.

E. In regard to the rejection of claims 8 and 9, which relate to the coil having an outer diameter greater than the main body of the catheter, the Examiner asserts "In modifying the invention of Rioux in view of Ressemann, the main body as taught by Rioux is surrounded by the coil as taught by Ressemann." March 30 Office Action, page 5, lines 12-14. Rioux has no coil, and his downstream restraint tube segment 20 is the same diameter as his upstream main catheter body 10. Nothing in Rioux has a diameter greater than the catheter. The coil 31 of Ressemann is embedded within the interior of the angioplasty catheter, and therefore it has the same or a smaller diameter compared to the diameter of the catheter. Being embedded within the catheter does not permit the coil 31 to have a greater diameter than the catheter. There is no evidentiary basis upon which to support the Examiner's assertion that the coil surrounds the main body. Only the Applicant explains a rationale for the coil being be larger than the main body.

F. The Examiner asserts that the "coiled section needs to be greater than the outer transverse dimension of the main body in order to be placed in a surrounding manner. In other words this property naturally flows from placing a coiled section about a

main body." March 30 Office Action, page 5, line 20-page 6, line 1. This assertion begs the question of obviousness by assuming that the important claim limitation is a natural property. There is no known natural property that dictates that the coil should be larger than the main body. The Examiner does not cite evidence of such a natural property. Indeed, Rioux and Ressemann teach the coil or restraint should be equal in size to or less than the size of the main catheter body. Even if it is necessary or desirable that the coil be wider than the main catheter body, it was the Applicant who discovered and applied this property, not Rioux or Ressemann. The Applicant's disclosure is the only evidence of this claim limitation.

G. In regard to the rejection stated in paragraph 8 of the March 30 Office Action, one relevant claim limitation among others is that the coiled section of the inflation tube extends around the exterior of the insertion tool connected to the catheter main body to maintain alignment of the inflation tube. "It is the Examiner's position that a helical tube 31 of Ressemann placed to surround a main body will also be concentric and maintain alignment." Page 10, lines 3-5. The helical tube 31 of Ressemann is embedded within the catheter itself. The helical tube 31 of Ressemann cannot both be embedded within the angioplasty catheter and on the exterior of the catheter. None of the cited references discuss using the coiled section of the inflation tube on the exterior of the insertion tool to maintain alignment of the inflation tube, because none of the cited references locate the inflation tube on the exterior of the insertion tool. There is no evidence to support the Examiner's position or the rejection. Only the Applicant teaches maintaining the inflation tube on the exterior of the insertion tool.

H. On page 13, lines 8-12 of the March 30 Office Action, the Examiner notes that Devonec's insertion mandrel, which extends through the center of the catheter, extends within the interior of reinforcing coils 52 formed in segments 9 and 11 of the catheter (Fig. 13). The reinforcing coils 52 of Devonec's catheter are located within the catheter, not on the exterior of the catheter as recited in the present claims. The fact that Devonec's insertion mandrel extends in the interior of the catheter does not make the catheter's internal components relocate to the exterior. Examiner's argument does not meet the scope of the claims.

I. As discussed in the preceding paragraphs G. and H., the Examiner's position is that it is obvious to locate the coiled section and the inflation tube on the exterior of the insertion tool, but at page 14, lines 19-22 of the March 30 Office Action, the Examiner states that it is an "advantage of a compact design avoiding interaction between pulling a cord and patient tissues. In other words, placing a cord within the tube avoids potential abrasion between a cord and the inner urethral surface." According to one rejection, there is motivation to include the coiled section and the inflation tube on the exterior of the connected catheter-insertion tool combination (even though the references do not teach this), but in another rejection the Examiner cites motivation to move external equipment inside to avoid abrasion. The Examiner cannot have it both ways. Only the Applicant teaches placing the coiled section and the inflation tube on the exterior of the connected insertion tool.

J. In paragraph 18 of the March 30 Office Action, the "Examiner notes that the coiled section of Devonec is provided as evidence that Devonec solves a similar problem." The internal coiled section of Devonec is to reinforce the tubular structure against collapse. See Devonec, column 5, lines 53-65. The embedded coil spring prevents the tubular sections of the catheter on opposite sides of the sphincter from collapsing. The coiled section of the present invention does not interact with any portion of a tubular catheter during normal use, because the main body of the catheter is upstream of the coiled section at a position upstream of the sphincter muscle. The problem that Devonec solves by the interior reinforcing coil is completely unlike the issue of providing restraint. Restraint against longitudinal movement in the urinary canal and reinforcement against axial collapse are not similar problems. The problems being entirely dissimilar, there can be no similar motivation for solving those entirely dissimilar problems. Basing the rejection on a motivation of solving similar problems is simply not supported by the invention and the cited references.

K. The Examiner erroneously assumes that Ressemann's helical tube 31 "is depicted as downstream relative to a catheter end." Paragraph 20, March 30 Office Action. Ressemann does not appear to describe whether the angioplasty catheter is inserted in an upstream direction or a downstream direction in a blood vessel.

Consequently, it is impossible to conclude that the helical tube 31 is downstream of the catheter end or is upstream of the catheter end. The direction of insertion would seem to be of no consequence, so long as the occlusion could be accessed and resolved, regardless of the direction of blood flow in the vessel. The Examiner has again relied on the Applicant's disclosure, not objective evidence from the cited references.

IV. Unique technical, use and economic improvements demonstrate the nonobvious nature of the claimed invention.

Numerous and significant technical, use and economic advantages and improvements result from using a coiled section of the inflation tube as a restraint against upstream movement. Some of those advantages and improvements are discussed below. Evidentiary support for many of these improvements is additionally found in Dr. Bolmsjö's Declaration, filed February 23, 2009, and in Dr. Schlein's Declaration, filed February 20, 2009.

A. The coiled section is an integral portion of the inflation tube. The pre-existing inflation tube in a partial-length catheter is also shaped as the downstream restraint, thereby eliminating the separate downstream restraint and eliminating labor-intensive manufacturing steps of creating the separate downstream restraint (e.g., tubular segment 20 in Rioux) and attaching it to the main body of the catheter (e.g. by ties 5 and 18 in Rioux). In contrast, forming a coiled section of the already-existing inflation tube does not require any more cost than a simple, easily-executed, and relatively straightforward technique of thermally forming part of the inflation tube into the coiled section. The significance of eliminating the extra part, minimizing manufacturing costs and related improvements are discussed in paragraphs 14 and 15 of Dr. Bolmsjö's Declaration.

B. All reputable manufacturers of medical products conduct a risk analysis on their products. A risk analysis considers possible ways that the product could fail. Rioux has considerably greater risks of failure, because it requires the additional tube segment 20 and the additional connection of the tube segment 20 to the main catheter body 10. A failure or malfunction of either of these features creates patient risk. In contrast, the coiled section of the inflation tube has fewer risks of failure, because no additional parts

are used, and no connection of additional parts is required. The significance of minimizing risks in medical products and the improvement from the present invention in doing so are discussed in paragraph 16 of Dr. Bolmsjö's Declaration.

C. The coiled section of the inflation tube contributes to eliminating or reducing the risks of urinary tract infection (UTI). Urine has natural germ and infection fighting characteristics. The coiled section allows the urine to flow over almost the entire surface of the urinary canal contacted by the coiled section, because the coils contact only a very small area of the urinary canal. The urine flushes almost the entire urinary canal by reaching between the individual coils. In contrast, the solid downstream tubular segment 20 of Rioux contacts and prevents the urine from reaching the considerably larger surface of the urinary canal contacted by the tube segment 12. Germs or bacteria located between the tube segment 20 and the urinary canal may grow and build up because the urine does not reach the canal surface contacted by the tubular segment 20. The sheath 32 surrounding the helical coiled section 31 of Ressemann, if applied in the urinary canal, would prevent urine from flushing germs and bacteria from the location where the sheath 32 contacts the urinary canal. Note that Ressemann is intended to be used in the germ-free environment of human blood, unlike the urine which surrounds the claimed catheter. The significance of avoiding bacteria and germ growth and the improvement provided by the present invention in doing so are discussed in paragraph 17 of Dr. Bolmsjö's Declaration and in paragraphs 22-25 of Dr. Schlein's Declaration.

D. The tube segment 20 of Rioux and/or the sheath 32 of Ressemann could become an obstruction to the passage of urine through the urinary canal, if they inadvertently turned sideways in the canal. The coiled section of the inflation tube cannot block the urine passageway through the urinary canal, even if the coiled section inadvertently turned sideways, due to the spaces between the individual coils. The significance of using the coiled section of the inflation tube to avoid inadvertent obstructions in the urinary canal is discussed in paragraph 18 of Dr. Bolmsjö's Declaration and in paragraph 24 of Dr. Schlein's Declaration.

E. The tube segment 20 of Rioux or the sheath 32 of Ressemann (if used in the urinary canal) is a possible source of irritation to the lining or mucosa of the urinary

canal, which might lead to an unusual sensation or low-level pain experienced by the patient. The inherent flexibility of the coiled section of the inflation tube provides more flexibility to avoid or minimize unusual sensation and irritation. The individual coils have significantly less surface contact with the lining or mucosa of the urinary canal than does the solid tube segment 20 of Rioux or the sheath 32 of Ressemann, thereby diminishing the amount of unusual sensation or irritation. The significance of using the coiled section of the inflation tube to avoid unusual sensation and low-level pain is discussed in paragraph 19 of Dr. Bolmsjö's Declaration and in paragraph 25 of Dr. Schlein's Declaration.

F. Removing the present partial-length catheter is easily achieved by pulling on the inflation tube after the balloon has been deflated. The coiled section of the inflation tube stretches out in length and collapses in a transverse dimension, which reduces or eliminates the amount of restraint and contact with the urinary canal during removal. In contrast, the solid tube segment 20 of Rioux or the coil 31 and sheath 32 of Ressemann do not have a similar collapse characteristic, and the full transverse sizes of these components must be dragged along the full length of the urinary canal during removal. Such dragging may cause irritation or pain or complicate removal. The significance of the coiled section of the inflation tube in facilitating removal of the catheter from the urinary canal while avoiding complications or significant irritation or pain is discussed in paragraphs 24 and 25 of Dr. Bolmsjö's Declaration and in paragraphs 25 and 38 of Dr. Schlein's Declaration.

G. The coiled section of the inflation tube makes it easier to restore the partial-length catheter to its intended position compared to Rioux, if the partial-length catheter should inadvertently migrate toward the bladder. Unexpected upstream migration of the Rioux catheter would carry the tube segment 20 through the orifice of the external urinary sphincter muscle to a position upstream of the sphincter muscle in the prostatic urethra or prostate gland. To restore the intended position, the orifice through the external urinary sphincter muscle must be expanded to allow the entire width of the tube segment 20 to pass downstream through it. However, medical intervention may be required to expand the orifice of the external urinary sphincter muscle sufficiently to return the tube segment

20 to the desired position. In contrast, pulling on the inflation tube of the present invention will move each coil through the external urinary sphincter muscle, without forcing the external sphincter muscle open. The width of the inflation tube remains constant as each coil moves through the orifice, and the sphincter muscle accommodates the tube width of each coil in the same way that the sphincter muscle constricts around the inflation coil to stop the flow of urine. An adverse situation similar to that of Rioux would occur with the sheath 32 of Ressemann, if Ressemann was applied in a urinary tract. Realistically, however, preserving normal functionality in unexpected conditions is irrelevant to Ressemann, because Ressemann is only used under conditions of intense medical supervision and control by medical practitioners, unlike the present catheter which will be used by the patient without medical supervision in day-to-day activities. The benefit of using the coiled section of the inflation tube as a downstream restraint to avoid pain and the medical procedures to restore the catheter to its intended use position, should it inadvertently move, is discussed in paragraph 26 of Dr. Bolmsjö's Declaration and in paragraphs 11, 12 and 17-19 of Dr. Schlein's Declaration.

H. If the tube segment 20 of Rioux should move inadvertently into the orifice of the external urinary sphincter muscle, the patient will not be able to control urination by normal constriction and dilation of the external urinary sphincter muscle. The tube segment 20 of Rioux will hold open the orifice in the sphincter muscle and allow urine to drain continuously, preventing self-control of urination. In contrast, if the coiled section of the inflation tube inadvertently moves into the orifice of the external urinary sphincter muscle, the sphincter muscle can still constrict between coils to terminate the flow of urine. The sphincter can also dilate to allow urine flow. Rioux may require a medical procedure to restore the proper position before normal urination can be resumed. The same would probably apply due to the sheath 32 of Ressemann, if Ressemann was applied in a urinary tract. The benefit of the coiled section of the inflation tube permitting self-control over urination even if the coiled section inadvertently moves into the orifice of the sphincter muscle is discussed in paragraph 27 of Dr. Bolmsjö's Declaration and in paragraphs 11, 12 and 19 of Dr. Schlein's Declaration.

I. The coiled section of the inflation tube also makes sizing less critical, because of the ability of the external urinary sphincter muscle to control urine flow even when the coiled section of the inflation tube is located in the orifice of the sphincter muscle, as discussed in point IV.H. above. A slight variation of length which may locate the coiled section of the inflation tube partially or wholly within the orifice of the external urinary sphincter muscle but the device is not prohibited from functioning as intended. In contrast, Rioux requires a precise length to assure that the tube segment 20 is completely downstream of the external urinary sphincter muscle to achieve normal urinary control. Many medical practitioners lack the necessary equipment, time and/or commitment to make accurate determinations of length of a partial-length catheter, so Rioux is less likely to be fitted correctly and therefore is less likely to function correctly, is more likely to require more attention from medical personnel, and is less likely to achieve patient satisfaction, compared to the present partial-length catheter which is less sensitive to dimensions. The same issues would likely arise due to the sheath 32 of Ressemann, if Ressemann was applied in a urinary tract. The benefit of the coiled section of the inflation tube in making sizing less critical and thereby facilitating use by a medical practitioner and achieving greater patient satisfaction is discussed in paragraphs 28 and 29 of Dr. Bolmsjö's Declaration and in paragraphs 17-19 of Dr. Schlein's Declaration.

J. Because of its relationship and similarity to a full-length catheter, and due to the coiled section of the inflation tube being separate from the main body and not interfering with a direct separable connection of a tube-type insertion tool, much of the same manufacturing equipment used for manufacturing full-length catheters can be used to manufacture the above partial-length catheter. Consequently, manufacturing costs are less, because a significant amount special manufacturing equipment does not need to be developed to make special parts. In contrast, the separate tube segment 20 and other unusual characteristics of Rioux, and the entire structure of the Ressemann angioplasty catheter, require manufacturing unique parts and assembling them separately, thereby increasing cost. The benefit of the coiled section of the inflation tube in facilitating use of conventional full-length catheter manufacturing equipment is discussed in paragraph 30 of Dr. Bolmsjö's Declaration.

K. The coiled section of the inflation tube makes it possible to take advantage of the existing experience of medical personnel to reduce the costs of inserting the device. Special equipment and execution of unfamiliar medical practices is required to insert and remove the Rioux device, compared to manipulating a conventional full-length catheter. Medical personnel have much prior experience with the insertion and manipulation of full-length catheters. The separated location of Rioux's downstream restraint tube segment 20 from the body of the partial-length catheter 10 requires a special insertion tool which must fit within the center of Rioux's catheter. Medical personnel must learn to use and manipulate such special tools. The additional special tools and the additional training required to insert the Rioux device increase the cost and complexity of using the Rioux device. In contrast, the preferred insertion tool for the present partial-length catheter is a length of flexible tubing. The external location of the coiled section of the inflation tube does not interfere with or otherwise prohibit a direct and separable connection of a tube-like insertion tool to the catheter main body. When that tubing is connected to the main body of the partial-length catheter at the separable connection, the assembly may be manipulated in substantially the same manner as a full-length catheter is manipulated. Medical personnel use essentially the same well-known insertion techniques to insert the present catheter as to insert a conventional full-length catheter. No special tools, additional training or new experience is required to insert the present catheter. As a consequence, costs of using the present catheter are lower compared to other devices which do not have similar insertion characteristics to a conventional full-length catheter. Risks and discomfort to the patient are minimized, because medical personnel insert full-length catheters with minimal risk or discomfort to the patient. The benefits of the present invention in allowing use of familiar medical practices and equipment is discussed in paragraphs 20-22 of Dr. Bolmsjö's Declaration and in paragraph 14 of Dr. Schlein's Declaration.

L. Typical prostate gland surgery requires inserting a full-length catheter immediately following surgery and keeping it in place for about three days, followed by removal of the full-length catheter and insertion and use of a partial-length catheter for about three weeks. The separable connection between the main body of the partial-

length catheter and the tubing-like insertion tool eliminates the need and the cost for two separate catheter insertion and removal procedures. The separable connection between the tube-type insertion tool and body of the partial-length catheter allows the connected combination to function as a full-length catheter for the first three days after prostate surgery until the patient has regained control of the external urinary sphincter muscle. Then, the tube-type insertion tool is disconnected from the body of the partial-length catheter at the separable connection, allowing the partial-length catheter to be used in its intended manner. The benefits of using a tube-like insertion tube to form a functional full-length catheter, followed by convenient separation to leave the partial-length catheter in place, thereby avoiding multiple significant medical procedures in favor of easily executed minor procedures, is discussed in paragraph 23 of Dr. Bolmsjö's Declaration and in paragraphs 14 and 15 of Dr. Schlein's Declaration.

Conclusion

For the reasons described above and in the Amendment and Response filed January 21, 2009, and others, it is believed that the obviousness rejections based on Rioux, Ressemann, Devonec and Ewers fail to meet the scope of the claims and/or have been formulated based on the impermissible use of hindsight. There is no substantial evidence to indicate that a person having ordinary skill in the art would combine the references as alleged by the Examiner. The nonobvious nature of the present invention is implicit from its significant improvements. Withdrawal of the obviousness rejections is respectfully requested.

If the Examiner still regards the pending claims as obvious and not patentable, the courtesy of a telephone call to the undersigned is requested.

Respectfully submitted,
/John R. Ley/
Registration No. 27,453
ATTORNEY FOR APPLICANT

Customer No. 28785

JOHN R. LEY, LLC
5299 DTC Boulevard, Suite 610
Greenwood Village, Colorado 80111-3327
Telephone: (303) 740-9000
Facsimile: (303) 740-9042